PART D GRIEVANCES, COVERAGE DETERMINATIONS, AND APPEALS

The process for resolving grievances, coverage determinations, and appeals under the Medicare Part D program is modeled after the Medicare Advantage program.

Grievances

Any complaint or dispute, other than one involving a coverage determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a plan sponsor.

- Enrollee may file a grievance with the plan orally or in writing.
- Enrollee must file a grievance within 60 days of the event that gives rise to the grievance.
- Enrollee must be notified of the decision no later than 30 days after the plan receives the grievance.
- If the grievance relates to a plan's refusal to expedite a coverage determination, the enrollee must be notified of the decision no later than 24 hours after the plan receives the grievance.

Coverage Determinations

The initial decision made by, or on behalf of, a Part D plan sponsor regarding payment or benefits to which an enrollee believes he or she is entitled.

An **exception** is a type of coverage determination that is unique to the Part D benefit. An enrollee may request a tiering exception or a formulary exception.

- Tiering Exception: Permits enrollees to obtain a non-preferred drug at the cost-sharing amount applicable to drugs on the preferred tier.

- Formulary Exception: Ensures that enrollees have access to medically necessary Part D drugs that are not included on a plan's formulary. Also permits enrollees to request an exception to a quantity or dose limit or a requirement that the enrollee try another drug before the plan sponsor will pay for the requested drug.

- Generally, a plan sponsor must grant an exception when the preferred or formulary drug for treatment of the same condition would not be as effective as the prescribed drug, would have adverse effects for the enrollee, or both.

- Plans are prohibited from requiring enrollees to seek additional exception requests for refills.

An enrollee, the enrollee's appointed representative, or the enrollee's prescribing physician may request a coverage determination by the plan sponsor.

A plan sponsor must notify an enrollee of its coverage determination as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving an expedited request, or 72 hours after receiving a standard request.

If a plan does not make a coverage determination within the applicable timeframe, the request must be forwarded to the independent review entity for review

Appeals

If a Part D plan sponsor makes an adverse coverage determination, the enrollee may request an appeal. There are five levels of appeal available in the following sequence:

- Redetermination by the Part D plan sponsor
  - Can make expedited requests orally or in writing; must make standard requests in writing
  - The enrollee must be notified of the decision no later than 72 hours after receiving an expedited request, or 7 days after receiving a standard request

- If a plan does not make a redetermination within the applicable timeframe, the request must be forwarded to the independent review entity for review

- Unfavorable decisions are appealable to the IRE

- Reconsideration by the independent review entity (IRE)
  - Expedited and standard requests must be made in writing
  - The enrollee must be notified of the decision no later than 72 hours after receiving an expedited request, or 7 days after receiving a standard request
  - Unfavorable decisions are appealable to a DHHS Administrative Law Judge (ALJ)

- Hearing with a DHHS ALJ
  - Hearing requests must be in writing; unfavorable ALJ decisions are appealable to the Medicare Appeals Council (MAC)

- Review by the MAC
  - Review requests must be in writing; unfavorable decisions are appealable to federal district court

- Review by a federal district court
  - Enrollee must file a civil action in federal district court